

SUPPORT FOR THE AMENDMENTS

Claim 19 was previously canceled.

Claims 1 and 3 are canceled herein.

Claims 2 and 4-10 have been amended.

Claims 31 and 32 have been added.

Support for the amendment of Claims 2 and 4-10 is provided by the corresponding claims as originally filed, the specification throughout (for example, at pages 3-4 and 7-14), and the Examples (for example, Examples 8-15). New Claims 31-32 are supported by original Claims 5 and 6 and the specification throughout (for example, at pages 3-4 and 7-14), and the Examples (for example, Examples 8-15).

No new matter has been added by these amendments.

REMARKS

Claims 2, 4-18, and 20-32 are pending in the present application.

The rejection of Claims 1-10 and 22-30 under 35 U.S.C. §112, first paragraph (written description – new matter), is obviated by amendment.

In the Office Action, the Examiner objects to the amendment of the claims as presenting new matter. The Examiner's position is that the steps: "removing a precipitate of insoluble components and said activated carbon by filtration" and "allowing said activate[d] carbon to absorb caffeine to selectively remove caffeine" are in the wrong order. The Examiner's position is that the specification does not provide any support for first removing the precipitate and activated carbon and subsequently absorbing caffeine. The Examiner states that the specification has this order reversed.

Applicants have amended the claims herein based on Examples 2 and 3, as well as the description at page 3, lines 9-18 and page 11, lines 3-12, for example. The claims now clearly articulate that the activated carbon is allowed to absorb caffeine to selectively remove caffeine.

Withdrawal of this ground of rejection is requested.

The rejections of: (a) Claims 15-18 under 35 U.S.C. §103(a) over JP 46-39058 together with Hara, (b) Claims 1, 3, 5-10, 22, 25, and 28 under 35 U.S.C. §103(a) over JP 46-39058 together with Hara and JP 2002-153211, and (c) Claims 2, 4-10, and 22-30 under 35 U.S.C. §103(a) over JP 46-39058 together with Hara, JP 2002-153211, and JP 6-128168, are respectfully traversed.

In the Office Action, the Examiner continues to maintain the obviousness rejections over JP 6-128168 and JP 46-39058, now with an explicit reliance upon Hara (US 4,613,672). Despite nearly 7 pages of remarks and reliance upon the Declarations filed on February 2, 2009 and October 14, 2009, the Examiner provides very little in response. The Examiner's basic position is that "it is inherent in JP 46-39058 that activated charcoal would be removed from the tea extract to fulfill the action of removing caffeine altogether from the tea extract" (see page 7 of the Office Action). The Examiner makes a similar allegation of inherency for the separation of acid clay from the tea extract. (see page 8 of the Office Action) Even if these steps are not inherent, the Examiner has taken the position that the removal of these materials would have been obvious. On pages 8-9 of the Office Action, the Examiner continues to defend the combination of Hara with the other cited references.

Specifically, Applicants again submit that at no point do JP 6-128168 or JP 46-39058 disclose or suggest dissolving a caffeine-containing catechin composition in a mixed solution of an organic solvent and water in a ratio ranging from 8/2 to 6/4 by weight as claimed. Nonetheless, the Examiner alleges that this limitation would flow from routine optimization as Hara (US 4,613,672) disclose that it is "well-known in the art to use a solvent solution of between 40 and 75% ethanol... to effectively extract catechins from tea extracts." The Examiner cites column 2 of Hara in support of this allegation; however, Applicants submit that Hara has no relevance to the case at hand. Specifically, Hara relates to the use of a 40 to

75% ethanol aqueous solution for the extraction of tea catechins from tea leaves. However, the extraction of tea catechins from tea leaves is unrelated to the use of the mixed solution in the claimed invention. Indeed, in the claimed invention, the mixed solution is used for dissolving a solid caffeine-containing catechin composition not for extracting tea catechins from tea leaves. As such, Hara does not compensate for the deficiencies in the disclosures of JP 6-128168 and JP 46-39058.

For sake of clarity, Applicants again submit the following with respect to the deficiencies in JP 6-128168 and JP 46-39058.

JP 46-39058 discloses a purified product of catechins can be obtained by taking the following steps: adding activated carbon to a catechin-containing solution obtained by extraction of tea leaves with water, acetone, ethanol and ethyl acetate, or to an alcoholic extract liquor of tea leaves, and then removing therefrom the resulting impurities (e.g. chlorophyll), followed by distillation of the solvent under a carbon dioxide gas atmosphere.

JP 06-128168 discloses that a powdered or concentrated product of tea catechins can be obtained by taking the following steps: preparing a tea extract by infiltration of dried tea leaves (100 parts by weight) into a solvent (300-600 parts by weight), or by heating tea leaves for 2 min to 12 hours, and then removing unnecessary by-products from the tea extract with activated charcoal, acid clay or diatomaceous earth before, and after, conducting a concentration of the alcoholic solution, followed by decolorization of the concentrated product.

The objective of JP 46-39058 is to produce an active agent in an extract liquor, apparently for addition to sea food. However, the Examiner alleges that the processing is the same (i.e., the starting material and the processing steps), as such, the desired objective (i.e., removal of caffeine and production of a green tea extract with caffeine removed) would be

inherently met. In other words, selective removal of caffeine is inherent to the contacting step and would be met by the art so long as the material contacted with the activated carbon (with or without acid clay or activated clay) contained caffeine.

First, at no point does JP 46-39058 disclose or suggest dissolving a caffeine-containing catechin composition in a mixed solution of ethanol and water in a ratio ranging from 8/2 to 6/4 by weight as claimed. The Examiner alleges that this limitation is met by treating 100 g of tea with 300 g of solution. However, this is clearly the incorrect ratio as the ratio in the claims is the ratio of the organic solvent to water. JP 46-39058 does not actually disclose any ratio of organic solvent to water.

Again, as was the case above, the Examiner's position related to JP 6-128168 is that the processing in JP 6-128168 is the same (i.e., the starting material and the processing steps), as such, the desired objective (i.e., removal of caffeine and production of a green tea extract with caffeine removed) would be inherently met. In other words, selective removal of caffeine is allegedly inherent to the contacting step and would be met by the art so long as the material contacted with the activated carbon (with or without acid clay or activated clay) contained caffeine.

Applicants disagree with this position by the Examiner and submit that at no point does JP 6-128168 disclose or suggest dissolving a caffeine-containing catechin composition in a mixed solution of an organic solvent and water in a ratio ranging from 9/1 to 1/9 by weight as claimed. Nonetheless, the Examiner alleges that this limitation would flow from routine optimization (citing Hara (US 4,613,672)).

As stated above, Hara has no relevance to the case at hand. Specifically, Hara relates to the use of a 40 to 75% ethanol aqueous solution for the extraction of tea catechins from tea leaves. However, the extraction of tea catechins from tea leaves is unrelated to the use of the

mixed solution in the claimed invention. Indeed, in the claimed invention, the mixed solution is used for dissolving a solid caffeine-containing catechin composition not for extracting tea catechins from tea leaves. As such, Hara does not compensate for the deficiencies in the disclosures of JP 6-128168 and JP 46-39058.

As was the case above for JP 46-39058, even if the Examiner were to take the position that the ratio of organic solvent to water is broad and obvious, the Examiner has not made out a proper case. A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) The Examiner has not offered any recognition in either JP 46-39058 or JP 6-128168 that the ratio of organic solvent to water is a result-effective variable. Thus, a *prima facie* case of obviousness has not been made.

Even if the ratio of organic solvent to water is a result-effective variable, the evidence provided in the Fukuda Declaration filed on February 2, 2009, clearly illustrate the criticality of the claimed range. Specifically, Applicants submit that even an allegation of obviousness would be rebutted by the experimental evidence illustrating the benefits of the claimed invention that are not disclose, suggested, or even predictable based on the disclosures of JP 46-39058 and JP 6-128168, which are presented in the Declaration under 37 C.F.R. §1.132 filed on February 2, 2009. In the Declaration filed on February 2, 2009, Applicants demonstrated the advantages of the claimed process which comprises treating a caffeine-containing catechin composition by use of a mixed solution containing an organic solvent and water at the specifically claimed ratio. In the Declaration filed on February 2, 2009, Applicants performed additional experiments using a mixed solution of ethanol and water

wherein the weight ratio of ethanol to water is more than 9/1. As shown in the Tables in paragraph 7 and summarized in paragraph 8 of the Declaration, mixed solution of an organic and water wherein the weight ratio of organic solvent to water is more than 9/1 have deteriorating color tone and also suffer from persistent bitterness.

Moreover, JP 6-128168 and JP 46-39058 disclose a method which entails contacting an alcoholic extract liquor of tea leaves with activated carbon (and acid clay or activated clay). It is questionable whether these methods are sufficient to improve the color tone (or hew) of a beverage, and also whether these methods are capable of efficiently removing caffeine from such compositions. To address these questions, Applicants conducted additional new experiments, which are presented in the Declaration under 37 C.F.R. §1.132 submitted October 14, 2009.

On the basis of the new data appearing in the Declaration under 37 C.F.R. §1.132 submitted October 14, 2009, the Declarant states:

As evidenced by Comparative Example 5' in the table appearing in paragraph 7 above, the purified product of alcoholic extract of tea leaves shows its absorbance to be 0.312, which is indicating the evidence that the hue of the product is extremely deteriorated, compared with the ones provided by Examples 2 and 3. Furthermore, the weight ratio of non-polymer catechins/caffeine after treatment is 4.55, from which it can also be said that the removal of caffeine is almost impossible where a tea extract is produced according to Comparative Example 5'.

Thus, it is concluded that the process of the present invention is significantly superior to the one described in JP 6-128168, by virtue of its specifically claimed multiple steps, which comprises dissolving a caffeine-containing catechin composition a 9/1 to 1/9 by weight mixed solution of an organic solvent and water, and then bringing the resultant solution into contact with activated carbon and allowing said activated carbon to absorb caffeine to remove caffeine.

In addition to the fact that JP 6-128168 and JP 46-39058 do not anticipate the claimed invention, Applicants remind the Examiner that "Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with

the prior art, can rebut *prima facie* obviousness. “Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness.” No set number of examples of superiority is required. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987)” Thus, the experimental data discussed above appearing in the Declaration filed on February 2, 2009, and the Declaration submitted October 14, 2009, clearly illustrates that substantial benefits flowing from the claimed method, which are enough to rebut a *prima facie* case of obviousness.

Despite the fact that at no point do JP 6-128168 or JP 46-39058 disclose or suggest dissolving a caffeine-containing catechin composition in a mixed solution of an organic solvent and water in a ratio ranging from 8/2 to 6/4 by weight as claimed, the Examiner alleges that this limitation would flow from routine optimization as Hara (US 4,613,672) disclose that it is well-known in the art to use a solvent solution of between 40 and 75% ethanol to effectively extract catechins from tea extracts.

The Examiner maintains that the evidence of record (i.e., the Declarations filed on February 2, 2009 and October 14, 2009) are insufficient to evidence of criticality for the ratio ranging from 8/2 to 6/4 by weight as claimed. Specifically, the Examiner argues that no evidence has been provided that this range offers any unexpected benefit as compared to ratios just outside this range. However, in so far as JP 6-128168 and JP 46-39058, even with Hara, fail to disclose or suggest the disclose or suggest dissolving a caffeine-containing catechin composition in a mixed solution of an organic solvent and water in a ratio ranging from 8/2 to 6/4 by weight as claimed, Applicants submit that the evidence of record is sufficiently commensurate and should be considered.

Indeed, the Examiner is reminded that “[a]lthough evidence of unexpected results must compare the claimed invention with the closest prior art, applicant is not required to

compare the claimed invention with subject matter that does not exist in the prior art. *In re Geiger*, 815 F.2d 686, 689, 2 USPQ2d 1276, 1279 (Fed. Cir. 1987). Further, the Examiner is reminded that the showing he is requiring is akin to the prohibited requirement of comparing “the results of the invention with the results of the invention” see, *In re Chapman*, 357 F.2d 418, 422, 148 USPQ 711, 714 (CCPA 1966).

In the response herein, Applicants have amended the claims to specifically require the combined use of activated carbon and acid clay. In view of the foregoing, Applicants submit that the Examiner has failed to set forth a proper *prima facie* case of obviousness. However, even if a *prima facie* case of obviousness did exist, evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. *In re Dillon*, 919 F.2d 688, 692-3, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990). “Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness.” No set number of examples of superiority is required. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987)”

To this end, Applicants refer to Examples 2 and 3 of the present application which use the activated carbon and the acid clay in combination, while in Comparative Example 3 only acid clay was used. As is evident from redacted Table 2 below (see page 43 of the specification), the single use of the activated carbon results in an insufficient effect due to the fact that the single use offers little effect of the caffeine removal.

Table 2 (redacted)

	Example	Example	Comp. Ex.
	2	3	3
Caffeine-containing catechin composition (g) ("POLYPHENONE HG", product to Tokyo Food Techno Co., Ltd)	100	300	100
Ethanol (g)	630	825.8	0
Water (g)	270	374.2	900
Activated carbon (g) ("KURARAY COAL GLC", product of Kuraray Chemical K.K.)	20	30	0
Acid clay (g) ("MIZUKA ACE #600", product of Mizusawa Chemical Industries, Ltd.)	100	30	100
Organic solvent/water (weight ratio)	70/30	71/29	0/100
Amounts of non-polymer catechins after treatment (wt%) ¹⁾			
GC (gallo catechin)	6.81	7.21	6.75
EGC (epigallo catechin)	32.08	29.74	31.75
C (catechin)	2.09	1.36	0.22
EC (epicatechin)	8.96	9.38	9.64
EGCg (epigallo catechin gallate)	37.12	37.76	35.93
GCg (gallo catechin gallate)	1.39	1.80	1.39
ECg (epicatechin gallate)	10.78	11.31	11.34
Cg (catechin gallate)	0.75	0.45	0.94
Non-polymer catechins/caffeine after treatment (weight ratio)	38.8	8.8	23.6
Amount of caffeine after treatment ²⁾ (mg/100 mL)	4.8	18.1	8.2
Content of gallates in non-polymer catechins after treatment (wt%)	50.0	51.3	49.6
Content of gallo catechins in non-polymer catechins after treatment (wt%)	77.4	76.5	75.8
Absorbance(-)	0.044	0.073	0.535
Evaluation of purified product	Caffeine was decreased, and hue and stability were both good.	Caffeine was decreased, and hue and stability were both good.	Hue was deteriorated, and a precipitate occurred

1) Composition of non-polymer catechins in "POLYPHENONE HG" preparation: GC (gallo catechin): 6.39%, EGC (epigallo catechin): 29.42%, C (catechin): 2.16%, EC (epicatechin): 10.3%, EGCg (epigallo catechin gallate): 37.13%, GCg (gallo catechin gallate): 1.93%, ECg (epicatechin gallate): 11.89%, Cg (catechin gallate): 0.79%; content of gallates: 51.73%, content of gallo catechins: 74.88%.

2) Amount of caffeine when "POLYPHENONE HG" was dissolved in water: 30.1 mg/100 g.

Further, as stated at page 44, lines 1-5 of the specification with respect to the data above:

As evident from the results in Table 2, the treatment of a caffeine-containing catechin composition by the present invention makes it possible to selectively remove caffeine while retaining the composition of catechins, and to obtain a catechin composition with an improved hue.

Applicants submit that the data above, taken together with the Declarations filed on February 2, 2009 and October 14, 2009 are clearly sufficient to rebut even a *prima facie* case of obviousness.

Another alternative would be to obtain an opinion from an expert in the tea processing art opining on the combinability of Hara and the cited JP references. In particular, this approach would focus on the Examiner's allegations on pages 8-9 of the Office Action and emphasize that in view of the differences between extraction of tea catechins (Hara) and purifying tea extract by removing caffeine from a tea extract (claimed invention) the artisan would not have found any reasonable basis to combine the disclosures of Hara with the cited JP references and/or any reasonable expectation of success of the claimed invention upon this combination.

Nonetheless, Applicants further submit that Hara relates to "catechin extraction from the tea leaves", whereas the present invention relates to "purification by a caffeine removal from a solid catechin extract". Accordingly; there is a difference between Hara and the present invention. Also, it is disclosed in Hara that "washing with chloroform removes the caffeine and chlorophyll", and that "if the pigments are not sufficiently removed, they can be removed by the activated carbon treatment". Thus, the skilled artisan would not first envision activated carbon treatment, if they read Hara. Also, for the purpose of caffeine removal, washing with chloroform is suggested to the skilled artisan, but the activated carbon treatment is not suggested.

With respect to Claims 7-9, Applicants submit that there is no basis for including these claims in the obviousness rejection over JP 46-39058 and JP 6-128168, even with Hara and/or JP 2002-153211. As is well-established, there is good reason for this deficiency in the rejections as these references do not disclose or suggest the specific method of producing the

caffeine-containing catechin composition for use in the claimed method. The same is true with respect to Claims 15-19, which correspond to Claims 7-9 and relate to the preparation step of a solid concentrate of a tea extract by purifying the same. As with Claims 7-9, there is no disclosure or suggestion in either JP 6-128168 and JP 46-39058, even with Hara and JP 2002-153211, of the specific steps defined in Claims 15-19. Further, the Examiner makes no attempt to provide any support for rejecting these claims. Accordingly, Claims 7-9 and 15-19 are improperly rejected.

In view of the foregoing, Applicants submit that the claimed invention is not obvious in view of JP 6-128168 and JP 46-39058, even with Hara and JP 2002-153211.

Accordingly, Applicants request withdrawal of these grounds of rejection.

Finally, with respect to the provisional obviousness-type double patenting rejections over copending US 10/581,200, Applicants make no statement with respect to the propriety of these rejections. Nonetheless, noting that it is not clear what scope of allowable subject matter exists in the present application or in the co-pending cited applications, Applicants request that these provisional obviousness-type double patenting rejections be held in abeyance. If it is determined that a Terminal Disclaimer is necessary, Applicants will consider filing the same at a later date.

The Examiner is reminded that MPEP §804 indicates that: "If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer." The present application has an effective filing date of October 27, 2003, which is earlier than the effective filing date of US 10/581,200 (i.e., December 1, 2004). As such, if this provisional

obviousness-type double patenting rejection is the only remaining rejection and US 10/581,200 remains pending, the Examiner shall withdraw the provisional obviousness-type double patenting rejection in this case and pass this application to allowance.


Applicants submit that the present application is now in condition for allowance.
Early notification of such action is earnestly solicited.

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